

For decades, California chose to reimburse providers for Abbott drugs -- apparently unlike any other Defendant in this case and apparently unlike any other state -- at “direct price.” Direct price is a term used in the marketplace by the pharmaceutical industry. California chose to simply read industry compendia and reimburse at that price, as reported therein, without further definition of the term. California now appears to regret that choice, but that does not render Abbott’s reporting of direct price to compendia “fraud.” Nor may California commandeer and redefine the term “direct price” to mean a discounted price, as it seeks to do. Such redefinition would constitute a direct regulation of the terms on which Abbott conducts its interstate commerce -- or at least unduly burden such commerce -- in violation of the dormant Commerce Clause. California’s direct price claims against Abbott must, therefore, be dismissed.

ARGUMENT

I. PLAINTIFFS FAIL TO ALLEGE THAT ABBOTT REPORTED “FALSE” DIRECT PRICES.

Plaintiffs summarily and conclusorily allege that Abbott reported false direct prices to industry pricing compendia. (*See* Compl. ¶ 5.) They have neither stated a claim for fraud under Rule 12(b)(6), nor plead with the particularity required by Rule 9(b). Nor could they: “direct price” does not mean anything specific in Medicare or Medicaid parlance, nor under California law. (*See* Abbott MTD at 1 n.1.) California, which admits that it was unusual -- if not unique -- in choosing “direct price” as its reimbursement benchmark (*see id.* at 1 n.2), merely took that price in the compendia as it found it. California cannot now be heard to complain that Abbott should have been reporting something else to those compendia.

California’s only response, a regurgitation of California regulations with misplaced emphases, does not show otherwise. Indeed, it confirms Abbott’s point: As California points out, 22 C.C.R. § 51513(a)(6) states that “Estimated Acquisition Cost (EAC) for a medical supply

product means the Average Wholesale Price [(“AWP”)] *or such other price as the Department determines* to be the price generally and currently paid by providers for a standard package.”

(Emphasis added.) The Department, in turn, did not use AWP for Abbott products; it “*determine[d]*,” instead, to reimburse at the compendia-reported “direct price.” By regulation, it declared that “[t]he [EAC] of all of the drug products manufactured or distributed by [Abbott] . . . shall be *the direct price for a standard package in the Department’s primary reference source*” -- i.e., a pricing compendium. *Id.* § 51513.5(a) (emphasis added). Though California now regrets this choice, it does not explain, let alone with the specificity required under Rule 9(b), how Abbott’s reporting of direct price to compendia constituted “fraud.”

II. CALIFORNIA’S ATTEMPT TO REGULATE THE MEANING OF “DIRECT PRICE” VIOLATES THE COMMERCE CLAUSE.

California’s attempt to hijack and redefine the industry term “direct price” to mean some discounted price also runs afoul of the dormant Commerce Clause, for either of two reasons. *First*, it is a *per se* impermissible attempt at direct regulation of interstate commerce. *See Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). To be clear: The applicable California regulations required that drug reimbursement be done at EAC -- and then defined EAC to mean “direct price” from an industry compendium. 22 C.C.R. §§ 51513(a)(6), 51513.5(a). California took that list price as it found it in the compendia, as do other Abbott customers nationwide. Now, however, California asserts that as to “direct price,” Abbott should have reported the “price generally and currently paid by providers” -- whatever that means.¹ In this way, California seeks to dictate the terms not only of *its* transactions with

¹ While drugs are, of course, sold at a range of prices, depending on a number of factors, California does not specify which should have been used to determine “direct price”; its position appears to be that it should have paid less, but its contentions are left at that vague level. (*See, e.g.*, Response to Abbott MTD at 1 (complaining that some other purchaser paid less) (citing Compl. Ex. A).)

Abbott, but also of those transactions and negotiations between Abbott and *all of its other customers* that use compendia-published “direct price.” This it may not do.²

Second, at the very least, California’s attempt to redefine “direct price” is an impermissible excessive burden on interstate commerce. *Pike v. Bruce Church, Inc.*, 397 U.S. 142 (1970). California could have satisfied its interest in setting Medi-Cal reimbursement rates with no impact on interstate commerce by setting its own independent regulatory benchmark, rather than co-opting “direct price.” California has not pleaded (and cannot plead) any justifiable need to *affect all other Abbott transactions*, nationwide, at direct price.

It is no answer for California to invoke the “market-participant” exception, which exempts state action “taken in a proprietary capacity as a purchaser or seller.” (*See Resp. to Abbott MTD at 4.*) California does not “purchase” the drugs at issue here; it reimburses for them. *See Pharm. Research and Mfrs. of Am. v. Concannon*, 249 F.3d 66, 80 (1st Cir. 2001) (“We hold that Maine does not fall under the market participant exception to the dormant Commerce Clause [because] Maine is not a market buyer of prescription drugs . . .”). Moreover, though California has latitude to reimburse for drugs based on its estimation of what providers pay (*see* 42 C.F.R. § 447.301), California seeks not just to set the terms of its *own* reimbursement, but to regulate commercial terms used by Abbott and its other customers by establishing an immutable legal definition of “direct price,” on pain of legal penalty to Abbott. That is well beyond mere market participation.³ Abbott’s Motion to Dismiss should be granted.

² *See Brown-Forman*, 476 U.S. at 582 (Statute offended dormant Commerce Clause because “[o]nce a distiller has posted prices in New York, it is not free to change its prices elsewhere in the United States”).

³ *See, e.g., United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgt.*, 261 F.3d 245, 255 (2d Cir. 2001) (“In general, a state regulates when it exercises governmental powers that are unavailable to private parties. . . . Classic hallmarks of government regulation include the threatened imposition of fines and/or jail terms to compel behavior.”).

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on April 3, 2006, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Toni-Ann Citera

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